



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,020	03/27/2003	Amarjit Singh	U 013943-5	9010
140	7590	07/27/2007	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			PRYOR, ALTON NATHANIEL	
ART UNIT		PAPER NUMBER		
1616				
MAIL DATE		DELIVERY MODE		
07/27/2007		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/089,020	SINGH ET AL.	
<b>Examiner</b>	<b>Art Unit</b>		
Alton N. Pryor	1616		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

**NO FEE IS DUE, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 30 April 2007.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1,2,4-11,15 and 18-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1,2,4-11,15,18,19 and 25 is/are rejected.

7)  Claim(s) 21-24 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/6/02.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's arguments filed 4/30/07 have been fully considered but they are not persuasive. See argument below.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,2,4-11,15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Skinhøj (WO 99/12524; 3/18/99). New claims 18,19 and 25 are added to this rejection. Skinhøj teaches a composition of an NSAID for peroral use comprising a fast release layer and an extended release layer, wherein said NSAID is present in both layers and in an amount ranging from 1 to 1600 mg. Skinhøj teaches that such a composition reduces the dose amount of active required on a daily bases as compared to a plain tablet. Skinhøj teaches that the composition can comprise a control release material such as cellulose derivatives, and excipients, plasticizers, calcium carbonate and fatty acids. Skinhøj teaches that the composition can exist in tablet form. Skinhøj teaches a number of NSAIDs including nimesulide. Skinhøj teaches that the fractions (fast release layer and extended release layer) can be coated. See abstract, page 9 lines 17-33, page 19 line 22 – page 20 line 27, page 21 lines 19-21, page 26 lines 28-29, page 35 lines 15-24, page 36 line 25 – page 38 line 32, claims 1, 11. Skinhøj does not disclose an example where nimesulide is employed in the composition

/ tablet. It would have been obvious to one having ordinary skill in the art to have employed nimesulide in the tablet / composition. One would have been motivated to do this in order to decrease the dosage amount of nimesulide given to a patient.

*Response to Applicants' argument*

Applicant argues that Claims 1 and 11 have been amended to define the immediate release layer and controlled release layer as single unit layers. However, WO 99/12524 discloses the first and second fractions comprise multiple units and a tablet of single units layers is not obvious from a reference (WO '524) that discloses fractions that comprise multiple units such as pellets. Examiner argues that multiple units are not excluded from the instant invention since the instant invention employs "comprising" language.

*Claim Objection*

Claims 20-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the instant invention comprising the fast release and slow release layers as defined in the claims.

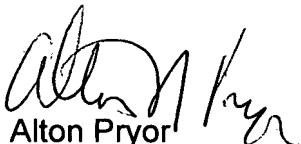
*Telephonic Inquiry*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alton Pryor  
Primary Examiner  
AU 1616